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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. APHIS-2017-0105]

RIN 0579-AE43

Evaluation and Recognition of the Animal Health Status of Compartments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to establish standards to allow us to recognize compartments for animal disease status, consistent with World Organization for Animal Health international standards. Under this proposed rule, when a foreign government submits a request for recognition of a compartment, we would conduct a disease risk assessment based on a list of eight factors that closely parallel those we use when conducting regionalization evaluations, and we would provide for public notice of and comment on the risk assessment. We would also add provisions for imposing import restrictions and/or prohibitions when a compartment we have recognized as disease-free experiences an outbreak and for lifting those sanctions once the outbreak has been controlled. These proposed standards would provide a tool that may be used to preserve international trade when regionalization is not feasible.

DATES: We will consider all comments that we receive on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0105>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2017-0105, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0105> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Rochette, Staff Officer, Regionalization Evaluation Services, Strategy and Policy, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7276; lisa.t.rochette@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92, “Importation of Animals and Animal Products; Procedures for Requesting Recognition of Regions” (referred to below as the regulations), set forth the process by which a foreign government may request recognition of the animal health status of a region. These regulations require that such requests be accompanied by information regarding the region that will enable the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture to evaluate the request.

In order to conduct a valid evaluation of a region's animal health status and any risk that may be associated with the action requested, it is important that APHIS have complete and pertinent information regarding the region, its disease history, its animal health practices and capabilities, and any effect its import practices or relationship to adjacent regions might have on disease risk. Using information provided by the government of requesting country or region, information obtained on site visits, and publically available information, we base our evaluations on our assessment of the following eight factors:

- Scope of the evaluation being requested;
- Veterinary control and oversight;
- Disease history and vaccination practices;
- Livestock demographics and traceability;
- Epidemiological separation from potential sources of infection;
- Diagnostic laboratory capabilities;
- Surveillance practices; and
- Emergency preparedness and response.

When regionalization is not feasible, compartmentalization is a tool that may be used to preserve trade. Compartmentalization is a procedure that a country may implement to define and manage animal subpopulations of distinct health status and under common biosecurity management within its territory, in accordance with the guidelines in the World Organization for Animal Health (OIE) Terrestrial Animal Health Code, for the purpose of disease control and international trade. Compartmentalization is distinct from regionalization, which involves the recognition of geographical zones of a country that can be identified and characterized by their level of risk for different diseases, but the two are not mutually exclusive.

While APHIS recently established domestic compartmentalization for primary poultry breeders under the National Poultry Improvement Plan, the regulations in part 92 do not provide standards for the recognition of compartments in countries or regions wishing to export live animals or animal products to the United States. Such standards are necessary to enable us to use compartmentalization as another tool, along with regionalization, to minimize trade disruptions in the event of a disease outbreak. We are therefore proposing to add requirements for the recognition of compartments for animal disease status to the regulations. The proposed requirements, which would closely track the existing ones for recognizing regions, would include a list of eight factors on which we would base our evaluations of the compartments and would provide for a process that would allow the public to review and comment on our risk documentation prior to our making a final determination on the status of a compartment under consideration. We would also provide for the imposition of restrictions and/or prohibitions when a compartment we have recognized as disease-free experiences an outbreak and for their removal once the outbreak has been controlled.

Adding such a process to the regulations would necessitate revising the current heading for 9 CFR part 92, which only covers regions. The revised heading would include a reference to compartments.

The existing regulations do not define *compartment*. We propose to add a definition of *compartment* to § 92.1 to read as follows: Any defined animal subpopulation contained in one or more establishments under a common biosecurity management system for which surveillance, control, and biosecurity measures have been applied with respect to a specific disease. The proposed definition is in keeping with the description of compartmentalization provided above.

Current § 92.2 contains requirements for recognition of a region for disease status. Paragraph (a) contains general procedures for a foreign government or APHIS to follow when initiating a request for such recognition. Paragraph (b) lists the information the requesting government is required to provide in order for APHIS to conduct the evaluation. Paragraph (c) lists the information required to support a request for APHIS to conduct an evaluation in order to recognize a foreign region as historically free of a disease. Paragraph (d) directs the reader to the lists maintained on the APHIS website of countries' and regions' disease statuses. Paragraphs (e) and (f) describe the process APHIS employs to allow the public to comment on its evaluations. Paragraph (g) states that if a region's request is granted, the region may still be required to submit additional information or allow APHIS to engage in additional information-gathering activities.

Since proposed § 92.2 would apply to compartments as well as regions, we would revise the section heading and several paragraphs that currently refer only to regions by adding references to compartments as well. We would revise paragraph (a) in this manner, thereby indicating that the general procedures for initiating a market request would apply for compartments as well as for regions. We would also update the address to which foreign governments would submit their requests for recognition of regional or compartmental disease status.

Paragraphs (b) and (c) would continue to apply only to regions. We are not proposing to make any substantive changes to those paragraphs. However, we are proposing to redesignate current paragraphs (d), (e), (f), and (g) as paragraphs (e), (g), (h), and (i), respectively, and add new paragraphs (d) and (f).

In new paragraph (d), we are proposing to list the factors on which we would base our evaluation of a compartment for disease status. As is the case for regions, the requesting government would need to submit information, in English, that APHIS would use to assess the compartment on each factor. The proposed paragraph would also provide a hyperlink and a mailing address for the foreign government to use to obtain more detailed information regarding the specific types of data that will enable APHIS to most expeditiously conduct an evaluation of the request. The factors we would evaluate are:

- Scope of the evaluation being requested;
- Veterinary control and oversight of the compartment;
- Disease history and vaccination practices;
- Livestock or poultry commodity movement and traceability;
- Epidemiologic separation of the compartment from potential sources of infection;
- Surveillance;
- Diagnostic laboratory capabilities; and
- Emergency preparedness and response.

With one exception, which will be discussed in detail below, these eight proposed factors very closely parallel the existing ones for recognition of regions listed in current paragraphs (b)(1) through (8). We would, however, specifically reference compartments in proposed paragraphs (d)(2) and (5), respectively, which would consist of the second and fifth bulleted items above.

Current paragraph (b)(4) requires the national government(s) requesting an evaluation of a region for disease status to submit information to APHIS regarding livestock demographics and traceability in the region. We do not believe that by simply incorporating the language from that

paragraph, we could necessarily obtain the information we need in relation to compartments. Instead, proposed paragraph (d)(4) would require the submission of information on livestock or poultry commodity movement and traceability into, within, and out of the compartment, paying particular attention to protocols that must be followed at each of these phases to allow for such movements. That information would aid us in determining how the compartment under consideration would keep its animal population separate from the rest of the animal population in the country or region within which the compartment exists. Unlike current paragraph (b)(4), proposed paragraph (d)(4) would not refer to livestock demographics, a factor that the limited scope of compartmentalization risk assessments would render largely irrelevant. In most cases, the compartment we would be evaluating would comprise a set of vertically integrated farm(s), feedmill(s), and other production sites (e.g. hatcheries) encompassing one species, along with associated commercial outputs managed by one company. The compartmentalized animal subpopulation/species would be distinct from the livestock population outside of the compartment.

In new paragraph (f), we propose to state that a list of countries that have requested an APHIS compartmentalization evaluation, and a description of the requested compartment(s), would be available in a document posted to:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request. This proposed paragraph is similar to current paragraph (d) (which would be redesignated as paragraph (e)), which pertains to the information we would make available to the public on regions requesting a status evaluation.

Current paragraph (g) (which would be redesignated as paragraph (i)) states that if a region is granted animal health status under the provisions of this section, that region may be

required to submit additional information pertaining to its animal health status or allow APHIS to conduct additional information-gathering activities in order for that region to maintain its animal health status. Under this proposed rule, the provision would apply to compartments as well; therefore, we would revise the paragraph by adding references to compartments where appropriate.

Current § 94.4 contains requirements for interim disease status designations, i.e., the imposition of importation restrictions and/or prohibitions when there is a disease outbreak in a region we have previously recognized as free of a disease, for a subsequent reassessment by APHIS of the region's status, and for the reestablishment of its previous disease-free status when the outbreak has been controlled and the prohibitions or restrictions are no longer needed. As indicated in § 92.4(a), when such an outbreak occurs, APHIS will take immediate action to prohibit or restrict imports from the entire region or, if appropriate, a portion of it, will assign an interim disease-status designation to the region or portion thereof, and will notify the public of the status change via a notice in the *Federal Register*. As stated in § 92.4(b), APHIS may subsequently conduct a reassessment of the disease situation in the region. Prior to taking any action to relieve the prohibitions or restrictions we have imposed, we will make information regarding our reassessment of the region's disease status available to the public for comment via a notice in the *Federal Register*. Paragraph (c) states that based on the findings of our reassessment and the comments we receive on the initial notice, we may publish a second notice in the *Federal Register* announcing our determination or, if needed, another document in the *Federal Register* requesting additional comments.

Since the proposed requirements in § 92.4 would apply to entire regions, portions of regions, and compartments, we would add references to compartments, as appropriate, throughout the section.

Miscellaneous

In current § 92.2 paragraphs (a), (b), (c), and (d), there are mailing addresses and/or URLs that are outdated. We would update that information. In addition, as explained previously, our proposed additions of new paragraphs (d) and (f) to § 92.2 necessitate the redesignation of current paragraphs (d), (e), (f), and (g) as paragraphs (e), (g), (h), and (i), respectively. In newly redesignated paragraph (e), we would make an editorial change to eliminate possible confusion about who may make a request for evaluation of disease status. In newly redesignated paragraph (g), we would revise references to other paragraphs in § 92.2 to reflect the redesignations.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This proposed rule is not expected to be an Executive Order 13771 regulatory action because this proposed rule is not significant under Executive Order 12866. Further, APHIS considers this rule to be a deregulatory action under Executive Order 13771 as the action is intended to minimize trade disruptions and could thereby provide benefits to producers and consumers.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER

INFORMATION CONTACT or on the Regulations.gov website (see ADDRESSES above for instructions for accessing Regulations.gov).

We are proposing to establish standards to allow us to recognize compartments for animal disease status, consistent with OIE international standards. This proposed rule would add compartmentalization as an option for evaluating disease status, but would not propose a specific implementation of this option.

The potential economic effects of imports based on a compartmentalization approach would depend on the disease status evaluation specific to the particular commodity and facility and the expected volume of the commodity that would be imported under this option. Under this proposed rule, we would perform a risk analysis to evaluate the animal health status of a compartment, as we currently do when evaluating regions. If after conducting the evaluation, we deemed the risk of importing animals or animal products from that compartment in accordance with the regulations to be acceptable, we would publish a notice in the *Federal Register* announcing the availability of the risk documentation for public review and comment.

Because this proposed rule would not include the implementation of any specific compartmentalization decisions, there are no costs or cost savings that would directly result from this action. Gains could be realized when compartmentalization is implemented, however, because it may serve as a means of minimizing trade disruptions.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection requirements included in this proposed rule have already been approved by the Office of Management and Budget under control number 0579-0040.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects in 9 CFR Part 92

Animal diseases, Imports, Incorporation by reference, Livestock, Poultry and poultry products, Region, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 92 as follows:

PART 92—IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS AND COMPARTMENTS

1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701;
7 CFR 2.22, 2.80, and 371.4.

2. The heading of part 92 is revised to read as set forth above.

3. Section 92.1 is amended by adding in alphabetical order a definition of *Compartment* to read as follows:

§ 92.1 Definitions.

* * * * *

Compartment. Any defined animal subpopulation contained in one or more establishments under a common biosecurity management system for which surveillance, control, and biosecurity measures have been applied with respect to a specific disease.

* * * * *

4. Section 92.2 is revised to read as follows:

§ 92.2 Application for recognition of the animal health status of a region or a compartment.

(a) The representative of the national government(s) of any country or countries who has the authority to make such a request may request that APHIS recognize the animal health status of a region or a compartment.¹ Such requests must be made in English and must be sent to the Administrator, c/o Strategy and Policy, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231. (Where possible, include a copy of the request and accompanying information in electronic format.)

(b) Requests for recognition of the animal health status of a region, other than requests submitted in accordance with paragraph (c) of this section, must include, in English, the

¹Additionally, APHIS may choose to initiate an evaluation of the animal health status of a foreign region or compartment on its own initiative. In such cases, APHIS will follow the same evaluation and notification procedures set forth in this section.

following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737.

- (1) Scope of the evaluation being requested.
- (2) Veterinary control and oversight.
- (3) Disease history and vaccination practices.
- (4) Livestock demographics and traceability.
- (5) Epidemiological separation from potential sources of infection.
- (6) Surveillance.
- (7) Diagnostic laboratory capabilities.
- (8) Emergency preparedness and response.

(c) Requests for recognition that a region is historically free of a disease based on the amount of time that has elapsed since the disease last occurred in a region, if it has ever occurred, must include, in English, the following information about the region. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737. For a region to be considered historically free of a disease, the disease must not have

been reported in domestic livestock for at least the past 25 years and must not have been reported in wildlife for at least the past 10 years.

- (1) Scope of the evaluation being requested.
- (2) Veterinary control and oversight.
- (3) Disease history and vaccination practices.
- (4) Disease notification.
- (5) Disease detection.
- (6) Barriers to disease introduction.

(d) Requests for recognition of the animal health status of a compartment must include, in English, the following information about the compartment. More detailed information regarding the specific types of information that will enable APHIS to most expeditiously conduct an evaluation of the request is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request or by contacting the National Director, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737.

- (1) Scope of the evaluation being requested.
- (2) Veterinary control and oversight of the compartment.
- (3) Disease history and vaccination practices.
- (4) Livestock or poultry commodity movement and traceability.
- (5) Epidemiologic separation of the compartment from potential sources of infection.
- (6) Surveillance.
- (7) Diagnostic laboratory capabilities.

(8) Emergency preparedness and response.

(e) A list of those regions for which an APHIS recognition of their animal health status has been requested, the disease(s) under evaluation, and, if available, the animal(s) or product(s) the region wishes to export, is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request.

(f) A list of countries that have requested an APHIS compartmentalization evaluation, and a description of the requested compartment is available at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request.

(g) If, after review and evaluation of the information submitted in accordance with paragraph (b), (c), or (d) of this section, APHIS believes the request can be safely granted, APHIS will indicate its intent and make its evaluation available for public comment through a document published in the *Federal Register*.

(h) APHIS will provide a period of time during which the public may comment on its evaluation. During the comment period, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself. Once APHIS has reviewed all comments received, it will make a final determination regarding the request and will publish that determination in the *Federal Register*.

(i) If a region or compartment is granted animal health status under the provisions of this section, the representative of the national government(s) of any country or countries who has the authority to make a regionalization or compartmentalization request may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional

information collection activities in order for that region or compartment to maintain its animal health status.

(Approved by the Office of Management and Budget under control number 0579-0040)

5. Section 92.4 is revised to read as follows:

§ 92.4 Reestablishment of a region or compartment's disease-free status.

This section applies to regions or compartments that are designated under this subchapter as free of a specific animal disease and then experience an outbreak of that disease.

(a) *Interim designation.* If a region or a compartment recognized as free of a specified animal disease in this subchapter experiences an outbreak of that disease, APHIS will take immediate action to prohibit or restrict imports of animals and animal products from the entire region, a portion of that region, or the compartment. APHIS will inform the public as soon as possible of the prohibitions and restrictions by means of a notice in the *Federal Register*.

(b) *Reassessment of the disease situation.* (1) Following removal of disease-free status from all or part of a region or a compartment, APHIS may reassess the disease situation in that region or compartment to determine whether it is necessary to continue the interim prohibitions or restrictions. In reassessing disease status, APHIS will take into consideration the standards of the World Organization for Animal Health (OIE) for reinstatement of disease-free status, as well as all relevant information obtained through public comments or collected by or submitted to APHIS through other means.

(2) Prior to taking any action to relieve prohibitions or restrictions, APHIS will make information regarding its reassessment of the region's or compartment's disease status available to the public for comment. APHIS will announce the availability of this information by means of a notice in the *Federal Register*.

(c) *Determination.* Based on the reassessment conducted in accordance with paragraph (b) of this section regarding the reassessment information, APHIS will take one of the following actions:

(1) Publish a notice in the *Federal Register* of its decision to reinstate the disease-free status of the region, portion of the region, or compartment;

(2) Publish a notice in the *Federal Register* of its decision to continue the prohibitions or restrictions on the imports of animals and animal products from that region or compartment; or

(3) Publish another document in the *Federal Register* for comment.

Done in Washington, DC, this 28th day of March 2019 .

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

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